# EUROPEAN STARCH ASSOCIATIONS

AAC - ASSOCIATION DES AMIDONNERIES DE CÉRÉALES DE L'UE UFE - UNION DES FÉCULERIES DE POMMES DE TERRE DE L'UE

> Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, room 1061 Rockville, MD 20852 USA

Brussels, 4 April 2003

RE: Regulations on "Registration of food facilities" (Section 305-Docket N° 02N-0276) and on "Prior notice of imported food shipments" (Section 307-Docket N° 02N-0278)

The European starch industry (AAC/UFE) would like to size the opportunity given to all exporters to the US to send you comments and questions regarding the two regulations that will be implemented as from 12 December 2003: "Registration of food facilities" and on "Prior notice of imported food shipments".

The AAC/UFE supports all the comments and remarks made by the Confederation of the EU Food and Drink Industries (CIAA) regarding these two regulations and therefore decided to complement them with the enclosed additional comments and questions.

The main issue for our industry is to find a solution regarding products that can be used in both food/feed and non-food/feed applications. It is highly important to avoid that when products are exported for non-food/feed applications, these are submitted to the provisions set in these two regulations.

In addition, we would like to underline that a good exchange of information between US Customs and the FDA is necessary. In fact, the regulation on prior notification requests most of the data that are already provided to Customs, which will only be technically in a position to share this data with the FDA in 2005. Therefore, in the meantime, operators will have to supply twice almost the same information, which is costly for the industry.

As you can notice from the CIAA comments and the enclosed remarks, we are concerned by these new import measures, as we do believe that these represent a serious additional administrative workload and cost for European exporters to the US, which makes them additional non-tariff barriers to our exports.

Thank you in advance for taking our concerns into account.

Yours sincerely,

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Managing Director AAC

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Secretary General UFE

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AAC - ASSOCIATION DES AMIDONNERIES DE CÉRÉALES DE L'UE UFE - UNION DES FÉCULERIES DE POMMES DE TERRE DE L'UE

AAC/UFE questions/comments on the US Regulations concerning : "Registration of food facilities" (Section 305 – Docket N° 02N-0276) "Prior notice of imported food shipments" (Section 307 – Docket N° 02N-0278)

In addition to the comments made by the Confederation of the EU Food and Drink Industries (CIAA), the AAC/UFE has the following remarks and questions:

#### 1. General questions and remarks on both Regulations

- Who will be considered as responsible for a possible terrorism act that would tamper with the products exported?
- How is e-commerce concerned by such Regulations?
- We understand that ingredients for materials in contact with food should normally not be concerned by these Regulations because they will be subject to further processing, e.g. cationic starches for paper and board production that will further be processed into paper. How FDA will make a distinction between products that are exported for food/feed applications and those for non-food/feed applications that are not covered by these Regulations?
  - This is particularly important for our sector as we produce products that are used for both food/feed and non-food/feed applications. A provision should be made to allow the exporter to indicate on the shipping documents when a product is exported for use in non/feed-food applications in order to exempt it from these Regulations. It should be included in both Regulations by setting a standard formula such as "This product is not concerned by Regulation N°....". This procedure will avoid that products are unduly blocked at the US port of entry.
- If imported products are unduly held at the US port of entry, how will financial compensation be paid to foreign exporters?

#### 2. Registration of food facilities

- It is provided that a contact person in each facility should be available at any time in case of emergency.
  - → We believe that this request is cannot be met as it means that a person has to be available 24 hours/24 hours and 365 days a year. The FDA should be more flexible and leave companies to decide how they want to be organised internally. In addition, there can be concerns regarding the language barrier.

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### 3. Prior notice of imported food shipments

- In case a shipment is made of products originating from different countries, a prior notice is requested for each originating country.
  - → This measure is administratively very burdensome and should be simplified.
- It is foreseen that a change to initial prior notice and the submission of a new prior notice in case of anticipated arrival should be done: 1 hour of more earlier than originally submitted or 3 hours or more later than originally submitted.
  - → For different reasons that are out of the control of operators (e.g. weather, transport problems, ...), it should be clearly said in the Regulation that in case of "force majeure" there is no need to modify the prior notices.